

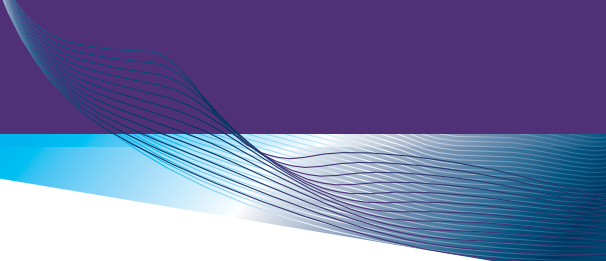


Renal Cryoablation

A clinically proven, minimally invasive
treatment for kidney cancer

Being diagnosed with kidney (renal) cancer can be an incredibly stressful time, but medical advances mean that today, the chances of you beating the disease are better than ever before.

This booklet has been developed, printed and distributed as an educational service. While every reasonable care has been taken to ensure accuracy in compiling the content for this booklet, it is for informational purposes only and is not intended to provide medical advice. Always consult a physician regarding the diagnosis and treatment of any medical condition.



Historically, the only option was surgery to remove either the whole kidney (nephrectomy) or the part of the kidney where the tumor was located (partial nephrectomy). Now, there are treatments available which require only small incisions or none at all. This booklet is designed to provide you with more information on one of these treatments – cryoablation.





Renal cancer

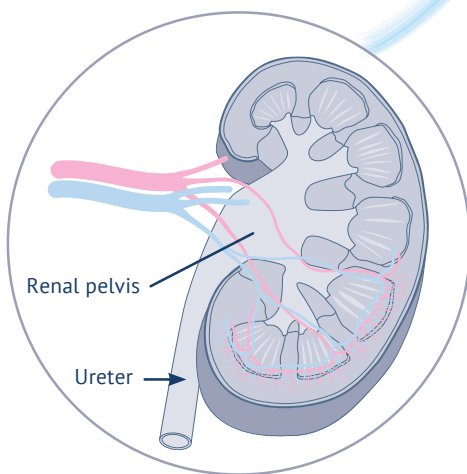
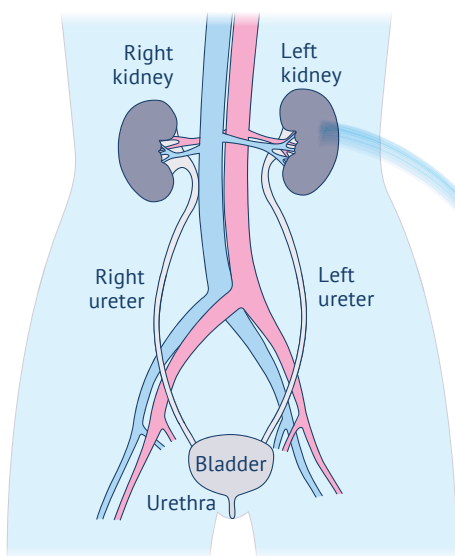
Renal cell carcinoma (RCC) is also called renal or kidney cancer. Kidney cancer is among the 10 most common cancers in both men and women.¹ RCC is more commonly found in men between the ages of 50-70 but can be diagnosed in anyone. The number of people being diagnosed with kidney cancer is increasing, but it has been suggested that this is due to more tumors being identified during routine scans and better testing, rather than more people actually getting kidney cancer. After being diagnosed with kidney cancer, your physician will determine if it has spread (and if so, how far) using a process called staging. This will help your physician understand how to treat the cancer and the right treatment option.

Understanding the renal anatomy

The kidneys are bean-shaped organs, each about the size of an adult fist.¹ Most people have two kidneys, and they are located in the lower back, one on either side of the spine.

The main job of the kidneys is to filter blood coming in from the renal arteries to remove excess water, salt, and waste products.¹ These substances are then excreted from the body in the form of urine.

The kidneys also help control blood pressure and help make sure the body has enough red blood cells.¹



What is cryoablation?

Cryoablation uses extremely cold temperatures to create ice that physicians can shape or sculpt to surround and kill the tumor^{2,3} while preserving surrounding tissues. For patients who are suitable for cryoablation, it offers many benefits, including

- Over 15 years of published data supporting its safety and effectiveness²
- Proven effectiveness of 95% of targeted renal tumors³⁻⁶
- Preserves renal function by protecting healthy tissue⁷⁻⁸
- A minimally invasive option:
 - Small to no incisions
 - Low complication rate with minimal discomfort^{5,9-11}
 - Excellent recovery time, with short or no hospital stay and rapid return to normal activities^{5,8,12}
- May be suitable for
 - Multiple tumors^{5,8,11}
 - Large tumors (up to 7cm)^{6,8,10}
 - Repeat treatments (after previous cryotherapy or after another treatment such as surgery)^{13,14}
 - Tumors which are positioned close to structures which might risk being damaged with other types of treatment^{8,9,12,15,16}



Is cryoablation right for me?

You should discuss with your physician whether cryoablation is a treatment option for you.

Only a physician experienced in cryoablation procedures can confirm if you are a suitable candidate for cryoablation. The size and location of your tumor(s) and your general health will all be factors in the decision. Discuss with your physician all the options that are available to you and how they compare to cryoablation.

What are the risks and side effects of cryoablation?

Your physician will advise you that any medical procedure has risks associated with it.

However, cryoablation avoids many of the risks and complications of other therapies, particularly surgery.

How is cryoablation performed?

There are two approaches used to treat kidney tumors with cryoablation; the type chosen will depend on your physician's judgment, and the location and size of the tumor(s) to be treated.

- **Percutaneous kidney cryoablation**

An image-guided procedure using CT (computerized tomography) or MRI (magnetic resonance imaging) technology to give the physician a clear view of the area to be treated. The quality of imaging technology allows the physician to accurately insert the cryoablation probes through the skin into the kidney tumor, carefully position them and control the creation of the ice to help make sure all of the tumor is treated.

- **Laparoscopic kidney cryoablation**

A laparoscopic, or keyhole, procedure is performed through three or four small incisions. A tiny camera is inserted into the abdominal cavity through one of these small incisions. The camera allows the physician to have excellent visibility, position the probes, and to accurately control the size, shape and location of the ice. The position and size of the ice will also be checked by a special ultrasound scan to help make sure all of the tumor is treated.



Will I be given anesthesia?

Renal cryoablation can be done under conscious sedation or under general anesthesia. Discuss with your physician the best option for you.

What happens during the procedure?

After an approach is chosen and anesthesia is given, one or more needles are then inserted through the skin and into the tumor. Ice is created at the needle tip by delivering argon gas under pressure through the needle shaft. The size and shape of the ice is controlled by the physician, who can closely monitor the process using imaging technology, and special equipment and software that regulates the freezing process and the temperature of the ice.

The tumor is frozen to a temperature which kills it. In most cases, the physician will shape the ice to also destroy a small safety margin of tissue around the tumor, while preserving as much healthy kidney tissue as possible to minimize impact on renal function.

Sometimes, depending on the location of the tumor, water or gas is used to move nearby structures (e.g. bowel) away from where the ice will be delivered to avoid any potential damage.



How long does the procedure take?

Although each case is different, a case using the percutaneous approach typically lasts one to two hours while a laparoscopic kidney cryoablation procedure usually takes between two-and-a-half to three hours.

What happens to the tumor once it has been frozen?

The cryoablation freezing process destroys the cells in the tumor, so there is no need to remove this dead tissue. The body's own immune system recognizes the cells are dead and sends white blood cells to clear them away. Once this process is complete, only scar tissue remains inside the body where the tumor was previously located.



How will I feel after the procedure?

Often patients are asked to take it easy for one to two days after the procedure, but many return to normal activity the next day.

How long will I need to stay in the hospital?


Length of stay will vary by patient and procedure. Typically patients will be discharged the day of the procedure, however some physicians may prefer their patients to stay for at least one night after a cryoablation procedure.

Will my insurance cover this procedure?

Consult your insurance carrier to find out the specific criteria for coverage. The reimbursement specialist at your physician's office may also be able to help you with this.

Glossary of Terms

Ablation:	The destruction of tissue by the application of extreme cold, heat or light (laser therapy which requires use of photo-sensitive drugs).
Anaesthesia:	The loss of sensation and usually of consciousness artificially produced by the administration of one or more agents that block the passage of pain impulses along nerve pathways to the brain.
Artery:	Blood vessel that carries blood away from the heart.
Cancer:	A malignant and invasive growth or tumor.
Conscious Sedation:	An induced state of sedation characterized by a minimally depressed consciousness such that the patient is able to continuously and independently maintain a patent airway, retain protective reflexes, and remain responsive to verbal commands and physical stimulation.
Cryoablation (Cryotherapy):	The destruction of tissue by the application of extremely cold temperatures.
CT:	Computerized tomography. Imaging technology which uses a computer to generate very clear 3-D images of the internal organs from a series of cross-sectional pictures, taken at very close intervals.
General anesthesia:	A medically induced coma and loss of protective reflexes resulting from the administration of one or more general anesthetic agents.
Incision:	A cut through the skin used in surgery. Conventional surgery requires large incisions to allow full access to the area to be treated, while laparoscopic or keyhole surgery requires just tiny incisions, through which specially designed instruments are passed.
Laparoscopic partial nephrectomy (LPN):	A minimally invasive procedure which involves the surgical removal (cutting out) of the diseased part of the kidney while the healthy part of the kidney remains in the body.
Laparoscopy:	A minimally invasive surgical procedure which involves passing a tiny camera through a small incision in the abdomen to allow the surgeon to visualize the area to be treated. Laparoscopy avoids the need to open up the abdomen with a large incision, as required with conventional surgery.
Malignant:	Describes a condition which has a tendency to become progressively worse, frequently used to mean cancerous.
Minimally invasive:	A procedure which avoids open surgery, requiring only very small surgical incisions or none at all, and which offers lower complication rates and faster recovery times than conventional surgery.
MRI:	Magnetic resonance imaging technology – uses magnetic fields and radio waves to give very detailed pictures of the internal organs.
Nephron:	Filtration unit within the kidney. Each kidney contains many nephrons and they are essential to the kidney being able to carry out its filtration and fluid-balancing function.
Nephron-sparing:	Describes a procedure which removes diseased kidney while leaving nephrons which are unaffected by the disease in place, so the kidney can continue to function.
Percutaneous:	Through the skin. In percutaneous kidney cryoablation, MRI, CT or ultrasound scanning allows the operator to clearly see the internal organs, and probes are passed directly through the skin into the kidney. Percutaneous procedures avoid the need to open up the abdomen with a large incision, as required with conventional surgery.
Recurrence:	The return of cancer after treatment and after a period of time during which the cancer cannot be detected.
Renal:	Related to the kidney(s).
Renal cell carcinoma (RCC):	The most common form of kidney or renal cancer, accounting for approximately 85% of cases.



Indications for Use: The Galil Medical Cryoablation Systems are intended for cryoablative destruction of tissue during surgical procedures; various BTG ancillary products are required to perform these procedures. The Systems are indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery (with the exception of cardiac tissue), ENT, gynecology, oncology, proctology and urology. These Systems are designed to destroy tissue (including prostate and kidney tissue, liver metastases, tumors, skin lesions and warts) by the application of extremely cold temperatures. A full list of specific indications can be found in the respective User Manuals.

Contraindications: None known.

Warnings and Precautions: A thorough understanding of the technical principles, clinical applications, and risks associated with cryoablation procedures is necessary before using BTG products to conduct cryoablation. Use of such products should be restricted to use by or under the supervision of physicians trained in cryoablation procedures with a BTG Cryoablation System.

The physician is solely responsible for all clinical use of the cryoablation needle and for any results obtained by use of the system. All clinical decisions prior to and throughout the cryoablation procedure shall be made by the physician based upon his/her professional opinion. Training on appropriate use of a BTG Cryoablation System is required prior to conducting cryoablation with a BTG System. Additional product specific warnings and precautions may be found in the Instructions for Use provided with each product.

Potential Adverse Effects: Potential adverse events which may be associated with the use of cryoablation may be organ specific or general and may include, but are not limited to abscess, adjacent organ injury, allergic/anaphylactoid reaction, angina/ coronary ischemia, arrhythmia, atelectasis, bladder neck contracture, bladder spasms, bleeding/ hemorrhage, creatinine elevation, creation of false urethral passage, cystitis, death, deep vein thrombosis (DVT), delayed/non healing, diarrhea, disseminated intravascular coagulation (DIC), ecchymosis, edema/swelling, ejaculatory dysfunction, erectile dysfunction (organic impotence), fever, fistula, genitourinary perforation, glomerular filtration rate elevation, hematoma, hematuria, hypertension, hypotension, hypothermia, idiosyncratic reaction, ileus, impotence, infection, injection site reaction, myocardial infarction, nausea, neuropathy, obstruction, organ failure pain, pelvic pain, pelvic vein thrombosis, penile tingling/numbness, perirenal fluid collection, pleural effusion, pneumothorax, probe site paresthesia, prolonged chest tube drainage, prolonged intubation, pulmonary embolism, pulmonary insufficiency/failure, rectal pain, rectourethral fistula, renal artery/renal vein injury, renal capsule fracture, renal failure, renal hemorrhage, renal infarct, renal obstruction, renal vein thrombosis, scrotal edema, sepsis, skin burn/frostbite, stricture of the collection system or ureters, stroke, thrombosis/thrombus/embolism, transient ischemic attack, tumor seeding, UPJ obstruction/injury, urethral sloughing, urethral stricture, urinary fistula, urinary frequency/urgency, urinary incontinence, urinary leak, urinary renal leakage, urinary retention/oliguria, urinary tract infection, vagal reaction, voiding complication including irritative voiding symptoms, vomiting, wound complication, and wound infection.

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